

Miracle-Ear®
Hearing Systems by Bausch & Lomb

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October 10, 2000

Honorable Donna Shalala
Secretary of Health and Human Services
200 Independence Avenue, S.W. Room 615F
Washington, D.C. 20201

Dear Secretary Shalala:

My name is Jim Newton, a small business owner in Ft. Collins, Colorado. I provide hearing aids and services to the hearing-impaired in a nine county area of Northeastern Colorado. At this point I am outraged that the U.S. Food and Drug Administration, after seven years of inaction, is planning to publish in the last few months of this administration, a totally ill-conceived and misdirected proposed rule governing the sale of hearing aids.

Hearing health care providers like me have been working with the FDA since 1993 to streamline the current FDA hearing aid regulations. Now, just weeks before the election of a new Administration, FDA is rushing to put forth a proposal that could eliminate hearing aid specialists like me from the marketplace. FDA reportedly favors allowing each state to determine the conditions for dispensing hearing aids. This will create inconsistency and confusion and will launch a 50-state effort by audiologists to install themselves as the sole gatekeepers to hearing health care without any medical or health policy justification.

Please take the time to consider the impact of this proposed hearing aid rule on the nation's millions of hearing-impaired and on the nation's small business hearing health care providers, as required by the Small Business Regulatory Enforcement Fairness Act.

Hearing impairment is a major health concern. Only approximately 20% of the 28 million hearing-impaired Americans who could benefit from a hearing aid, actually use one. The proposed rule that the FDA is advocating would impede access to needed hearing health care services for millions of Americans. Please don't let this happen.

Respectfully yours,

James A. Newton, BC-HIS
Board Certified in Hearing Instrument Sciences

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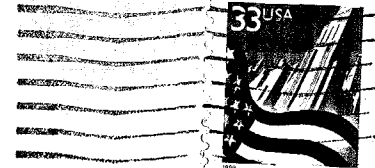
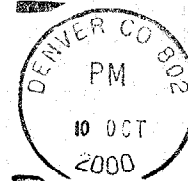
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